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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,521	08/28/2003	Edgar Hommann	33332/US	6807
7590	02/24/2005		<div>EXAMINER</div> <div>WILLIAMS, CATHERINE SERKE</div>	
David E. Bruhn DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498			<div>ART UNIT</div> <div>3763</div>	<div>PAPER NUMBER</div>
DATE MAILED: 02/24/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,521

Applicant(s)

HOMMANN ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Figures 1-4, and

Figures 5-6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7 and 11-17 are considered generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with David Bruhn on 2/3/05 a provisional election was made with traverse to prosecute the invention of group I, claims 1-8 and 11-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-10 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Additionally, upon review of the claims it was noticed that claims 8 and 18 contain limitations not included in the elected species. Specifically the limitation of “the locking means is configured to enable a controlled advancement of the piston by a fraction of the maximum piston stroke pre-set by the starting and end positions of the piston in the liquid container” and “the drive wheel moves incrementally when the locking means releases the drive wheel” are included in the species of figures 5 and 6 not the elected species of figures 1-4. See specification page 11 paragraph 1. Claims 8 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: “block-coiled” in claim 12 is not included in the specification of the application.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “flexible force transferring means being a cylindrical coil spring which is block-coiled in a region in which the coil spring is coupled to the drive mechanism” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities: the term “resets” in line 9 is not clear and precise. The term “reset” imparts to one skilled in the art that the device/mechanism is returning to the starting position of the device or the device is being returned to the starting configuration. This is how the term is commonly used in the syringe injector art. However, in the claims and the description, the term reset is being used to described the returning force of the spring to its resting state which actually causes the device to actuate the plunger and dispense the contents of the syringe. In actuality, the spring is not resetting the device but causing the actuation of the plunger. It is suggested that the term “reset” be explicitly defined in the specification or another term(s) be used to describe the way the spring is causing the actuation of the device and not a resetting of the device. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16 are rejected since it is unclear whether the claim limitation of “a restoring means” (claim 1), “a flexible force transferring means” (claim 16) and “locking means” (claim 16) fall within the scope of 35 U.S.C 112, sixth paragraph. These recitation are unclear because the means clause is followed by functional language but does not clearly recite “means for...”. Additionally, it is unclear if the restoring means is for applying a restoring force to the drive mechanism and the drive mechanism is for delivering liquid or the function of the restoring means includes “for delivering liquid from the container”. If applicant is invoking 112 6th

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paragraph, that intention must be expressed in the next correspondence, the claims should be amended to include clear “means for...” language, and the specification must clearly point out sufficient structure, material or acts for achieving the specified function. For the purposes of this office action, it is assumed that applicant is invoking 112 6th paragraph, means plus function interpretation. Additionally, it is assumed that the restoring means is for applying a restoring force to the drive mechanism for delivering liquid from the container.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7,11,13-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sealfon (USPN 5,261,882).

It is noted that the claim limitation of “flexible force transferring means” (claim 1) is not being interpreted as a means plus function limitation and that applicant is not invoking 112 6th paragraph since there is no functional language associated with the means recitation.

Conversely, the claim limitation of “flexible force transferring means” (claim 16) is being interpreted as a means plus function limitation and that applicant is invoking 112 6th paragraph due to the functional language following the means. Based on the specification and drawings, it

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is assumed that the corresponding structure for the flexible force transferring means is a flexible member that transfers the rotational movement into longitudinal movement of the piston and equivalents.

The claim limitation of “restoring means...applies a restoring force” (claim 1) is being interpreted as a means plus function limitation and that applicant is invoking 112 6th paragraph. (See 112 2nd paragraph above) Furthermore, based on the specification and drawings it is understood that the corresponding structure for applying a restoring force includes a spiral spring.

The claim limitation of “adjustable locking means for providing controlled locking” (claim 4) and “locking means” (claim 16) are being interpreted as means plus function limitations and that applicant is invoking 112 6th paragraph. Additionally, based on the specification and drawings it is understood that the corresponding structure for providing controlled locking includes a rocking lever having a blocking projection at its front end and the blocking projection is formed to correspond to and cooperate with a toothed area.

Regarding claims 1,2 and 16, Sealfon discloses a device (10) for the controlled delivery of an injectable liquid (36) from a liquid container (18) sealed at a rear end by a piston (26) which can slid axially in the container to deliver the liquid from an outlet (156) at a front end of the container. See figure 8. The device also includes a flexible force transferring means (interconnected spheres 80) which is axially deviated behind the container (18) away from a generally central longitudinal axis of the container. See figure 8. A drive mechanism (68) is coupled (via screw 90) to the flexible force transferring means (80) to axially advance the piston (26) for delivering the liquid (18). A restoring means spiral spring (helical coil 28) permanently

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applies a restoring force (see 3:63 and 4:25-33 for constant pulling force) to the drive mechanism (via the spring's connection with the drive mechanism through interconnected spheres 80, see figure 8) and resets it (that is the spring returns to its resting unenergized position) from a start position to an end position (see 4:51-59), thereby delivering liquid from the container.

Regarding claim 3, the drive mechanism includes a drive wheel and the flexible force transferring means is attached to a lateral facing area of the drive wheel. See figure 2 and 8.

Regarding claims 4-6 and 16, an adjustable locking means includes a rocking lever (136) having a blocking projection (96, see figure 10) at its front end and the blocking projection is formed to correspond to and cooperate with a toothed area (98) for providing controlled locking against angular adjustment of the drive wheel. See 4:48-50. The lever (134) is moveable to a releasing position in which the drive mechanism is released by advancing an operating button (100) and can be reset into a locking position in which the drive mechanism is locked by a second restoring means (not shown). See 4:50-59 and 6:1-4.

Regarding claim 7, figure 8 shows the attachment position (90) of the flexible force transferring means to the drive mechanism is substantially diametrically opposite the rear end of the liquid container (on the other side of the circular drive mechanism 68).

Regarding claims 13-14, a guide is formed by the concave portion (see figure 2) of the drive mechanism (68), the inner walls of both half casings (42,44) and a stay (76) that projects perpendicularly from the bottom casing (44) that prevents lateral bending of the transferring means because of its interconnected arrangement with the means (see 3:66-68). See figure 2.

Regarding claim 11, the drive mechanism (68) is configured to emit a number of audible clicks corresponding to the dosage delivered in that the prior art has the same structure as the

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instant invention and therefore meets the claim limitations even though the prior art does not specifically recite that clicks are produced. Specifically, the instant invention clicks are generated by the toothed area on the drive wheel contacting the blocking projection. The prior art drive wheel (68) has a toothed area (98) and contacts a blocking projection (96). The prior art structure and the fact that the elements engage one another in the way the claimed invention does, makes the prior art “configured to emit a number of clicks” even if the prior art does not specifically recite this feature.

Additionally, Sealfon shows the device in figure 1 attached at the front end to medical tubing that has a needle for well understood intravenous service. See Figure 1 and 2:63-65.

Claim Rejections - 35 USC § 103

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sealfon in view of Updike et al (USPN 4,568,335). Sealfon meets the claim limitations as described above but fails to include indicating the amount delivered by audible clicks.

Updike discloses a device for the controlled infusion of medications that includes a syringe with a piston. The device also includes the teaching of including audible clicks to indicate the delivery of a given volume of fluid. This feature enables the use of the device without direct viewing. See 3:47-53.

At the time of the invention, it would have been obvious to include the teaching of the audible click feature as taught by Updike into the invention of Sealfon. Both devices are for administration of medicaments into a patient; therefore, a combination is proper. Additionally, one skilled in the art would recognize the advantage of the teaching of audible clicks by Updike

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(see Updike 3:47-53) and incorporate the feature into the invention of Sealfon in order to enhance the usability of the device for the visually impaired.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sealfon in view of Douglas et al (USPN 6,482,186).

Sealfon meets the claim limitations as described above but fails to include the flexible force transferring means being a coil spring which is block-coiled in a region in which the coil spring is coupled to the drive mechanism.

Douglas discloses a medication delivery device that includes a flexible force transferring means that includes a cylindrical coil spring (3000) which is block-coiled (no reference number but coils are bunched together at the attachment point) at an end region for attachment to a plunger (60). See figure 2.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to use a cylindrical coil spring (as taught by Douglas) with a block-coiled region for attachment to the drive mechanism as a substitution for the flexible force transferring means of Sealfon. Both devices are analogous in the art of drug injectors and both teach mechanisms for a longitudinally diverted plunger. Additionally, applicant has failed to disclose that the flexible force transferring means being a coil spring with a block-coil serves any advantage, particular purpose, or solves a stated problem. Furthermore, one would have expected Sealfon's transferring means and the claimed cylindrical coil with the block-coiled region (see Douglas) to perform equally well because both structures would perform the same function, i.e. angular displacement from the longitudinal axis of the piston to reduce the overall profile of the device since both structures are designed to bend.

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Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sealfon in view of Utterberg et al (USPN 5,112,311). Sealfon meets the claim limitations as described above, including a teaching of a injection needle at the front end of the container, but fails to include specifically include a 30 or 31 gauge injection needle.

Utterberg discloses a winged IV infusion assembly that includes the general background teaching of a standard 30-gauge needle for administering IV fluids. See background 1:19-29.

At the time of the invention, it would have been obvious to one skilled in the art to incorporate the teaching of the 30-gauge needle by Utterberg into the invention of Sealfon. Sealfon discloses the use of a needle (see above) and Utterberg provides a specific needle for that purpose, i.e. intravenous fluid administration. Since both devices relate to intravenous fluid administration, a combination is proper. Additionally, 30-gauge needles are well known in the art and as evidenced by Utterberg are a standard gauge for IV injection. The motivation for the incorporation is found in both references in that Sealfon discloses a needle and Utterberg provides a specific needle for achieving the structure and function, i.e. iv fluid administration.

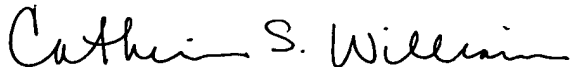
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
February 20, 2005